



Product Safety Notification

XX/XX/2008

To: Hospital Administrators
Managers of Radiology
Radiologists

RE: **Notification of Definium 8000 Field Modification – VolumeRAD Reconstruction**

GE Healthcare has recently become aware of an anomaly in the Processing Software on the Definium 8000 system that may impact patient safety when using the VolumeRAD advanced application (option). **Please ensure that all potential users in your facility are made aware of this safety notification and the recommended actions.**

Safety Issue The following Software anomaly has been identified in the VolumeRAD application: The slice visualization of VolumeRAD exams acquired on the Wallstand receptor will be offset by 17mm. For example, anatomy that physically exists at a distance of 50mm from the wallstand patient barrier (receptor cover) will be visualized in the slice image with an (wrongly) annotated distance of 33mm. More importantly, these software anomalies prevent the visualization of anatomy WITHIN a distance of 17mm from the wallstand patient barrier (receptor cover). This lost anatomy cannot be recovered or visualized by retrospective reconstruction processing.

Affected Product Definium 8000 with VolumeRAD option having control room PCs 5183547-28 or 5261133 and software collector 5147845-6 Rev 1.

Safety Instructions For exams that require the visualization of anatomy WITHIN 17mm of the wallstand patient barrier (receptor cover), place a 17mm spacer between the patient and the wallstand patient barrier (receptor cover) BEFORE acquisition. Note that this workaround cannot be retrospectively applied after the exam has been acquired.

Corrective Action A GE Healthcare Field Engineer will schedule a field visit to install a software modification. This software modification will be performed at no charge. The modification will require between 1 and 2 hours to install, depending on system configuration.

Contact Information If you have any questions/concerns regarding this issue, please contact us immediately:
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Please be assured that GE Healthcare is constantly making every effort to maintain a high level of safety and quality in every system shipped. GE Healthcare regrets any inconvenience that this issue may cause.

Sincerely,

General Manager Regulatory Affairs, Diagnostic Imaging
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